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10/528,665	09/16/2005	Scott Harrington	86941/SLP	4036

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EXAMINER
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ART UNIT	PAPER NUMBER
2624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/528,665	HARRINGTON ET AL.
	Examiner	Art Unit	
	SHEELA C. CHAWAN	2624	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>18 December 2008</u>.

2a)☒ This action is FINAL.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-28</u> is/are pending in the application.

  4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) <u>19 and 20</u> is/are allowed.

6)☒ Claim(s) <u>1-18, 21- 28</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

  a)☐ All   b)☐ Some * c)☐ None of:

  1.☐ Certified copies of the priority documents have been received.

  2.☐ Certified copies of the priority documents have been received in Application No. _____.

  3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>2/09/09</u>.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____

5)☐ Notice of Informal Patent Application

6)☐ Other: _____

DETAILED ACTION

Response to Amendment

1.   Applicant's amendment filed on 12/18/08 has been entered and made of record.

Claim 28 is new claim.

Claims 1- 28 are pending in the application.

Response to Arguments

2.   Applicant's arguments filed on 12/18/08 have been fully considered but they are

not persuasive.

3.   In the remark, applicants have argued in substance that

1.   Roehrig 902 is no indication of the criteria or features used by the CAD

analysis to determine the probability. The use of a probability value by itself cannot

anticipate or make obvious the coded descriptors of the claimed invention which provide

information on one or more criteria used by the CAD analysis to identify the CAD-

detected abnormalities.

In the reply, the examiner states the following.

As to point 1, with respect to the art rejection, the examiner has carefully

considered applicant's argument, but firmly believes the cited reference to reasonably

and properly meet the claimed limitation. The examiner does not agree with the remarks

that Roehrig 902 is not teaching or no indication of the <u>criteria or features</u> used by the

CAD analysis to determine the probability. The use of a probability value by itself cannot

anticipate or make obvious the coded descriptors of the claimed invention which provide

information on one or more criteria used by the CAD analysis to identify the CAD-

detected abnormalities. (Fig 10 and paragraph 0055 explains digitized mammography

image 1040 is sent through abnormal feature detection stage 1050 of CAD system

1020. Key components of abnormal feature detection stage 1050, abnormal feature

extraction sub-stage 1051 and classifier sub-stage 1052 have been described in detail

in said U.S. patents and applications incorporated by reference herein. The output of

abnormal feature extraction sub-stage 1051 is usually the features and location

information of the detected suspected abnormalities. The results from abnormal feature

detection stage 1050 are in the form of two-dimensional annotation map or x-y

coordinate information 1055 of the locations of the CAD detected suspected

abnormalities that have probability values of being abnormal that are above a certain

selected threshold, see paragraph 0056). There is no specific definition in the claim

regarding "coded descriptor", examiner defines" coded descriptor", are list of

suspicious location in the digital mammogram images which correspond to suspicious

lesions i.e. possibly cancerous lesions, see paragraph 0044, also see paragraph 0049,

defines" coded descriptor", are group of coded color pixels which may be highlighted

with a particular color such as white or red to identify or considered suspicious pixel.

However, applicant is reminded that the claim language is given its broadest reasonable

interpretation. Therefore, Roehrig 902 teaches the above limitation.

Information Disclosure Statement

4.   The information disclosure statement (IDS) submitted on 2/09/09 the

information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

5.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another

filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States

and was published under Article 21(2) of such treaty in the English language.

Claims 1- 10, 15-18 and 21- 28, are rejected under 35 U.S.C. 102(e) as being

anticipated by Roehrig et al., (US.20020097902 A1, Listed in IDS).

As to claim 1, Roehrig discloses a method for displaying results of a computer

aided detection (CAD) analysis of a digital image (abstract), the method comprising:

i) analyzing the digital image using CAD analysis to identify one or more CAD-

detected abnormalities (paragraph 0031, 0034, fig 10, and paragraph 0055 explains

digitized mammography image 1040 is sent through abnormal feature detection stage

1050 of CAD system 1020. Key components of abnormal feature detection stage 1050,

abnormal feature extraction sub-stage 1051 and classifier sub-stage 1052 have been

described in detail in said U.S. patents and applications incorporated by reference

herein. The output of abnormal feature extraction sub-stage 1051 is usually the

features and location information of the detected suspected abnormalities. The results

from abnormal feature detection stage 1050 are in the form of two-dimensional

annotation map or x-y coordinate information 1055 of the locations of the CAD detected

suspected abnormalities that have probability values of being abnormal that are above a

certain selected threshold, see paragraph 0056);

ii) generating one or more coded descriptors for said CAD-detected abnormalities

wherein said coded descriptors provide information on one or more criteria used by said

CAD analysis to identify said CAD-detected abnormalities (paragraph 0056, 0059 and

0072, note There is no specific definition in the claim regarding "coded descriptor",

examiner defines" coded descriptor", are list of suspicious location in the digital

mammogram images which correspond to suspicious lesions i.e. possibly cancerous

lesions, see paragraph 0044, also see paragraph 0049, defines" coded descriptor", are

group of coded color pixels which may be highlighted with a particular color such as

white or red to identify or considered suspicious pixel); and

iii) displaying said digital image with the one or more coded descriptors

(paragraph 0057, 0058).

As to claim 2, Roehrig discloses the method as claimed in claim 1 wherein said

digital image is a digitized image of an X-ray film (paragraph 0030, fig 5, 502).

As to claim 3, Roehrig discloses the method as claimed in claim 1 wherein said

digital image is a digital mammogram (paragraph 0031, 0051).

As to claim 4, Roehrig discloses the method as claimed in claim 1 further

comprising visually analyzing said digital image to identify one or more user-detected

abnormalities, said visual analysis being performed before said step of displaying and

wherein said user-detected abnormalities are re- assessed based on said information

provided by said coded descriptors (fig 5, 506, paragraph 0034, 0045, 0053, 0056, 0059
and 0072).

As to claim 5, Roehrig discloses the method as claimed in claim 4 wherein
said digital image is a digitized image of an X-ray film and wherein said visual
examination is performed on said X-ray film (paragraph 0075).

As to claim 6, Roehrig discloses the method as claimed in claim 1 further
comprising visually analyzing said digital image to identify one or more user-detected
abnormalities said visual examination being performed with said coded descriptors
being displayed simultaneously such that a user can refer to said coded descriptors
while performing said visual analysis (paragraph 0009, 0053 and 0075).

As to claims 7 and 22, Roehrig discloses the method as claimed in claim 6
wherein said digital image is a digitized image of an X-ray film and wherein said visual
examination is performed on said X-ray film (paragraph 0043, step 100, paragraph
0009 and 0053).

As to claims 8 and 23, Roehrig discloses the method as claimed in claim 1
wherein said one or more coded descriptor displayed in the image is selected by a user
(paragraph 0049, step 804, paragraph 0043).

As to claims 9 and 10, Roehrig discloses the method as claimed in claim 1
wherein said coded descriptors also provide information on probability that said CAD-
detected abnormalities are indicative of a disease state (note, visual markings could be
used to indicate the abnormalities, paragraph 0045).

As to claim 15, Roehrig discloses the method as claimed in claim 14 wherein said highlighted feature is selected from size, brightness, location, density, number and length of spicules (paragraph 0050, note last sentence providing a closeup view or selected area of the image).

As to claim 16, Roehrig discloses the method as claimed in claim 14 wherein said highlighted feature comprise individual calcifications within a micro- calcification cluster (fig 9, paragraph 0051).

As to claims 17 and 18, Roehrig discloses the method as claimed in claim 10 wherein said visual markers are color coded according to said probability that the CAD-detected abnormalities are indicative of a disease state (paragraph 0051 element 910 in fig 9).

As to claim 21, Roehrig (902) discloses a method for identifying abnormalities in a mammogram the method comprising:

i) analyzing said mammogram using Computer Aided Detection (CAD) analysis to produce CAD results, said results including one or more CAD- detected abnormalities and one or more coded descriptors for said CAD-detected abnormalities (paragraph 0056, 0059 and 0072, note There is no specific definition in the claim regarding "coded descriptor", examiner defines" coded descriptor", are list of suspicious location in the digital mammogram images which correspond to suspicious lesions i.e. possibly cancerous lesions, see paragraph 0044, also see paragraph 0049, defines" coded descriptor", are group of coded color pixels which may be highlighted with a particular color such as white or red to identify or considered suspicious pixel), wherein

said coded descriptors provide information on one or more criteria used by said CAD

analysis to identify said CAD-detected abnormalities (see fig 10, and paragraph 0055

explains digitized mammography image 1040 is sent through abnormal feature

detection stage 1050 of CAD system 1020. Key components of abnormal feature

detection stage 1050, abnormal feature extraction sub-stage 1051 and classifier sub-

stage 1052 have been described in detail in said U.S. patents and applications

incorporated by reference herein. The output of abnormal feature extraction sub-stage

1051 is usually the features and location information of the detected suspected

abnormalities. The results from abnormal feature detection stage 1050 are in the form of

two-dimensional annotation map or x-y coordinate information 1055 of the locations of

the CAD detected suspected abnormalities that have probability values of being

abnormal that are above a certain selected threshold, see paragraph 0056, fig 5,

element 504, paragraph 0044);

     ii) displaying said mammogram and a corresponding image of said mammogram

comprising said CAD results (fig 5, element 506, paragraph 0044);

     iii)visually analyzing said mammogram to identify one or more user-detected

abnormalities said visual examination being performed with said corresponding image

of said mammogram comprising CAD results being displayed simultaneously such that

a user can refer to said CAD results while performing said visual analysis (paragraph

0045).

     As to claim 24, Roehrig (902) discloses a system for displaying results of a

computer aided detection (CAD) analysis of a digital image said system comprising:

a digital image source (paragraph 0043, CAD system 100);

a processor for analyzing said digital image using CAD analysis to identify CAD-detected abnormalities (paragraph 0044);

a processor for extracting criteria used in said identification of CAD-detected abnormalities (paragraph 0044 step 804);

a processor for associating coded descriptors with said criteria and said abnormalities(paragraph 0044, 804 generates bit of abnormal regions which are associated with digitized mammograms);

a display for displaying said digital image and said coded descriptors (paragraph 0044, viewing 104 at step 506).

As to claim 25, Roehrig (902) discloses the system as claimed in claim 24 wherein said display comprises more than one display area (paragraph 0044, suspicious areas).

As to claim 26, Roehrig (902) discloses the system as claimed in claim 25 wherein a digital image is displayed in a first display area without coded descriptors and said digital image is displayed in a second display area with coded descriptors (step 908, without color coding , paragraph 0051, after step 910 color coding).

As to claim 27, Roehrig (902) discloses the system as claimed in claim 24 further comprising a means for displaying an analog X-ray film (paragraph 0052, actual radiographic film (analog film), paragraph 0053 radio logic image on a mammographic X-ray film screen imaging system.

Regarding claim 28, it is interpreted and thus rejected for the same reasons as applied above in the rejection of claim 1).

Claim Rejections - 35 USC § 103

6.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 - 14, are rejected under 35 U.S.C. 103(a) as being unpatentable over Roehrig et al., (US.20020097902 A1, Listed in IDS), as applied to claims 1- 10, 15-18 and 21- 28, above and further in view of Roehrig et al., (US. 7,054,473 B1).

Regarding claim 11, Roehrig (702) discloses method and system for the display of regions of interest in medical images. Roehrig is silent about wherein the alpha-

numeric information is based on Breast Imaging Reporting and Data System (BI-

RADS).

Roehrig (473) disclose method and apparatus for an improved computer aided

diagnosis system. The system comprises of:

wherein the alpha-numeric information is based on Breast Imaging Reporting and

Data System (BI-RADS), (column 3, lines 47- 54, note, data system for storing and

retrieving digitized mammograms and making a report on the diagnosis).

Therefore, it would have been obvious to one of ordinary skill in the art at the

time of the invention to have modified Roehrig (702)to include wherein the alpha-

numeric information is based on Breast Imaging Reporting and Data System (BI-

RADS). It would have been obvious to one of ordinary skill in the art at the time of the

invention to have modified Roehrig (702) by the teaching of Roehrig (473) in order to

determine a uniform display quality regardless of the original modality of the image(as

suggested by Roehrig (473) at column 1, lines 50- 54).

As to claim 12, Roehrig (473) discloses the method as claimed in claim 10

wherein said alpha-numeric information is a sentence describing in medical terms said

CAD-detected abnormalities (note, abnormalities indicated by annotation or labeling or

highlighting the ROI, column 3, lines 47- 54) .

As to claim 13, Roehrig (473) discloses the method as claimed in claim 10

wherein said visual markers comprise border delineations of regions (column 6, lines

44- 59 , the grey scale values are used to identify abnormal tissue for normal tissue

using pixel intensity variations).

As to claim 14, Roehrig (473) discloses the method as claimed in claim 10 wherein said visual markers comprise one or more highlighted feature used by CAD for determining likelihood of abnormality (note highlighting corresponds to tagging features , column 3, lines 33-35).

Reason For Allowance

7.   Claims 19-20 are allowed.

The following is an examiner's statement of reasons for allowance:

The present invention is directed towards a method for displaying result of a computer aided detection (CAD) analysis of a digital image. The prior art fails to teach or suggest wherein said visual markers can be displayed with varying degrees transparency, as required by claim 19.

8.   Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a). Applicant

is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

        A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event will the statutory period for reply expire later than SIX

MONTHS from the date of this final action.

Contact Information

9.   Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Sheela C Chawan whose telephone number is. 571-
272-7446. The examiner can normally be reached on Monday - Thursday 7.30 - 6.00.

        If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Brian Werner can be reached on 571-272-7401. The fax phone number for
the organization where this application or proceeding is assigned is 571-273-8300.

        Information regarding the status of an application may be obtained from the
Patent Application Information Retrieval (PAIR) system. Status information for
published applications may be obtained from either Private PAIR or Public PAIR.
Status information for unpublished applications is available through Private PAIR only.
For more information about the PAIR system, see http://pair-direct.uspto.gov. Should
you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).

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/Sheela C Chawan/

2/27/09

Primary Examiner, Art Unit 2624